## REMARKS

Claims 1-23 and 38-45 are pending in the application. Claims 12, 41 and 43 have been withdrawn from consideration as being drawn to a non-elected species as a result of an earlier election requirement. Claims 24-37 and 46-50 have been cancelled as a result of an earlier restriction requirement. Applicants retain the right to file a divisional application drawn to these cancelled claims. By the foregoing amendment, claim 38 has been amended to correct an obvious editorial error.

Pursuant to the April 23, 2003 Office Action, claim 38 stands objected to and claims 1-22, 13-23, 38-40, 42, 44 and 45 stand rejected.

**Claim Objections:**

As noted previously, claim 38 has been amended to correct an obvious editorial error identified by the Patent Office. In view of the amendment, the objection to claim 38 is believed to be fully addressed. Applicants respectfully request that the objection to claim 38 be withdrawn.

**Claim Rejections:**

Claims 1-22, 13-23, 38-40, 42, 44 and 45 stand rejected under 35 USC §103(a) as being unpatentable over Hagiwara et. al. (US 4,775,585) in view of Konagaya et. al. (US 6,013,275), Niira et al. (US 5,556,699) and Wada et. al. (US 3,981,970). The cited art is said to teach the following: 1) Hagiwara et al. teach the incorporation of antibacterial zeolite particles in polymers such as ABS; 2) Konagaya et al. teach that the antibacterial activity of silver zeolite can be increased by incorporating the same in a hydrophilic substance which is an organic compound or a high molecular compound containing at least one of a hydroxyl group, amino group, amide group, carboxyl group or alkali metal salts thereof; 3) Niira et al. teach silver zeolites further incorporating ammonium ions for the prevention of discoloration of resins into which they are incorporated and 4) Wada et al. teach ion-exchange mechanisms involving zeolites, especially silver zeolites. The Patent Office alleges that while the art does not specifically disclose a silver zeolite encapsulated with an acrylic resin, especially (hydroxyetheyl methacrylate) having an average diameter of about 2000 microns or less, optionally further comprising an ammonium salt or sodium nitrate or optionally further incorporated into an addition polymer, it does amply

suggest the combination of the silver zeolites and hydrophilic polymers and other polymers such as ABS as well as the use of ammonium ions and the exchange of silver with sodium ions and nitric acid. As such, the Patent Office alleges that it would have been well within the skill of the art and one skilled in the art would have been motivated to modify the prior art as noted with the expectation that increased antibacterial activity would arise from the combination of the silver zeolite and the hydrophilic polymer, that the ammonium ions would inhibit discoloration of polymer resins such as ABS and that the addition of sodium nitrate would drive the release of silver ions, thereby increasing the amount of silver ions available for antibacterial activity. In conclusion, it is alleged that the claimed invention as a whole would have been prima facie obvious to one skilled in the art at the time the invention was made because each element of the invention has been collectively taught by the combined teachings. Applicants respectfully traverse the rejection and requests reconsideration.

The present invention is directed to novel antimicrobial agents comprising a particulate hydrophilic polymer having encapsulated therein certain antimicrobial active agents, especially silver zeolites. These particles have a high concentration of antimicrobial active agent and a small particle size so as to optimize their ability to be incorporated into other polymer matrices without, or with minimal, impact upon the physical properties of the polymer matrix into which they are incorporated. In one aspect, the invention relates to individual antimicrobial active agent particles, e.g., a single antimicrobial zeolite particle, coated with a hydrophilic polymer coating, much like the candy coating of an M&M, where in our case the zeolite corresponds to the chocolate. An alternative embodiment is where a multitude of individual antimicrobial active agent particles are dispersed in a small amount of a hyrdophilic polymer creating a large reservoir of antimicrobial active comprising all of the encapsulated antimicrobial active agent particles. Conceptually, this embodiment could be represented either by a peanut cluster where the peanuts correspond to the zeolite particles for those embodiments having a high weight ratio of antimicrobial agent to hydrophilic polymer or by pieces of a Nestle Crunch bar where the crispies correspond to the antimicrobial agent in those embodiments where the aforementioned weight ratio is lower.

The selection of the specific form in which the novel antimicrobial agent is used is in part determined by the application to which it is to be applied. For example, coatings would more likely employ the individually encapsulated antimicrobial active agent particle or the smaller of

the cluster type particles so that they do not protrude above or too far above the surface of the coating on and underlying substrate. In this respect, coatings for catheters to be inserted into a patient need to be as smooth as possible to avoid irritation in use. On the other hand, large molded parts, especially for use in a high water exposure environment, would use larger particles so as to ensure a large reservoir of antimicrobial active materials as well as a greater likelihood that a portion of the particle would touch the surface.

From the foregoing, it is clear that the particle size is important. Generally speaking, the novel, particulate antimicrobial agents according to the present invention are not likely greater than about 3000 microns. These particles can be compounded into other polymers at high concentration to form masterbatches or at lower concentrations for commercial use in producing molded parts or integrated into coatings, etc. Generally speaking, the encapsulated antimicrobial agent remains as discrete domains in the polymer matrix: although there may be some break-up of the cluster type particles during polymer processing. Regardless, by virute of the encapsulation of the antimicrobial active agent with the hydrophilic polymer prior to incorporation into, for instance, a non-hydrophilic matrix polymer for manufacturing molded parts, Applicants have surprisingly found that one is now able to provide a longer life and greater release of antimicrobial agent for overall markedly improved antimicrobial efficacy at the same loading, of antimicrobial active agent, for the non-encapsulated agents. In hydrophilic polymer matrices of varying hydrophilicity values, different from that of the encapsulant material, the use of the microencapsulated materials enables one to more precisely control the release characteristics of the antimicrobial active in such matrices. The use of these novel additives provides better performance, more controlled performance at a lesser cost.

As noted above, the Patent Office acknowledges that the art does not specifically show the claimed invention but contends that it would be within the skill of one of ordinary skill in the art to make the modifications necessary to attain applicants' invention and with the expectation that one would attain the results as shown by Applicants. Depite these assertions, the Patent Office has neither shown any basis nor provided any argument as to what would have motivated one to do as Applicants have done or as to why there would be an expectation of the results Applicants have attained.

Applicants acknowledge the prior use of the non-encapsualted antimicrobial active agents as additives for polymer materials, including hydrophilic polymer materials. Applicants

also acknowledge that the release characteristic, and thus bioefficacy, of the antimicrobial agent in hydrophilic polymer is improved as compared to the same level of incorporaton in a non-hydrophilic polymer. As noted in the application and above, this is because in non-hydrophilic polymers the only available source of antimicrobial active is at the surface of the polymer material, regardless of whether it is a molded part, a film, a fiber, etc. Where mobility of the antimicrobial active is contingent upon water or some other carrier, if the matrix polymer prevents that carrier from reaching the active dispersed in the polymer, then the entrapped active (i.e., that active not at the surface) is rendered inert relative to providing antimicrobial activity to the article in which it is incorporated.

Applicants fully appreciate the teaching of both Hagiwara et. al. and Konoagaya et. al.; however, neither of these teach or make obvious the present invention. Both speak of making antimicrobial compositions and articles of those compositions wherein a non-encapsulated antimicrobial agent is incorporated into the relevant polymer matrix. Konagaya et. al. improve the antimicrobial activity by using hydrophilic polymer matrices, either as a true hydrophilic polymer, copolymer or blend. Even assuming the hydrophilic polymer matrices of Konagaya et. al. were equivalent to the hydrophilic encapsulating materials of the present invention, nothing in Konagay et. al.or Konagaya et. al. in view of Hagiwara et. al. would suggest, infer or motivate one to encapsulate an antimicrobial active agent in a polymer, in particulate form, and use such as an antimicrobial additive to be added to other polymer compositions for improved antimicrobial efficacy without materially/adversely altering the physical properties of the polymer into which it is incorporated.

Applicants' acknowledge the teaching of Niira et. al. relative to the addition of ammonium ions for improved color stability. However, nothing in Niira et. al, alone or combined with the other art would suggest, infer or motivate one to produce the encapsulated antimicrobial agents according to the present invention.

Finally, although it is not clearly stated, it is presumed that Wada et. al. is cited against that aspect of the present invention wherein a dopant is added to the encapsulating material. Wada et. al. teach the manufacture of zeolites and the use of those zeolites in recovering metal cations from an aqueous solution. With respect to the latter, it teaches the method by which the zeolites first pick up the metal ions (a method which is not wholly unlike that employed to charge the antimicrobial zeolites) and then the method by which the zeolites are initiated to

release and give up the metal ions for recovery. In the latter respect, as noted by the Patent Office, nitric acid is added to the solution to drive the release of the silver ions. However, nothing in Wada et al. suggest that various dopants, as taught by the present invention, could be added to a polymer encapsulant which is then used to coat or form clusters of zeolite or other ion-exchange material for the purpose of aiding or accelerating the release of the antimicrobial metal ions from the zeolite or other carrier upon the exposure of a polymer article in which the encapsulated antimicrobial agent is entrained to water or water vapor. Certainly, one would not envision attempting to incorporate nitric acid or other caustic materials into a polymer. Thus, is not believed that Wada et. al. provide any guidance or suggestion to the use of dopants in and in conjunction with the encapsulated antimicrobial agents of the present invention.

Contrary to the assertions of the Patent Office, none of the cited art, alone or in combination, speak of, suggest, infer or motivate one to produce the particulate, encapsulated antimicrobial agents of the presnt invention and employ them in polymer compositions for enhance antimicrobial efficacy and control. Consequently, applicants respectfully request that the rejections be withdrawn and the application, as amended above, be passed on to allowance.

**Petition For Extension of Time**

By this response, Applicants hereby petition for a three-month extension of time; thereby extending the response period from July 23, 2003 to and including October 23, 2003. Enclosed is payment of the Petition Fee in the amount of $475.00.

**Fees**

Enclosed is Credit Card Authorization in the amount of $475.00 as payment of the Petition Fee for the Petition for Three Month Extension of Time. No addition fees are necessary as no new claims have been added.

Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,

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